

TELEMETRIC *and* HOLTER ECG WAREHOUSE, ISSUE 3, JANUARY 2009:

This electronic Newsletter is a publication with updates about the activities of the Telemetric and Holter ECG Warehouse (THEW) Initiative at the University of Rochester (UR), NY.

THEW Update – January 2009

Opening of the THEW: The Telemetric and Holter ECG Warehouse is up and running!

The past couple of months of year 2008 have been crucial for our initiative because they have seen the completion and the validation of all technologies used to store, convert, manage and share the data in the Warehouse including clinical and electrocardiographic information. The development and validation of these technologies has been done in collaboration with private companies in order to ensure the Warehouse to be fully compliant with regulatory requirements (see the press releases below).

Today the THEW is open and operational (www.thew-project.org). We invite you to visit the download area of our website (www.thew-project.org/download.html) and send us a request for a **free demo version of the THEW Client Application**. With this demo software, one can connect to a demonstration database and learn about the tools we have developed and the types of data available. The demo database contains example of ECGs from thorough QT studies, ECG with recorded drug-induced torsades de pointes and recordings from healthy individuals.

Other important developments of these past months include the signatures of the data sharing agreements with two major pharmaceutical companies: Pfizer and Roche. These agreements defined the legal framework for sharing hundreds of Holter ECGs from two thorough QT studies in the THEW. Interestingly, one of them includes the recordings from all arms of the study i.e. baseline, placebo, moxifloxacin **and the tested drug that did reveal a positive QT signal and thus did not reach the market**. These two databases were recorded using different technologies and the ECGs from both studies have been successfully included in the Warehouse. As January of 2009, these two studies will be available to the THEW members.

From the resource and technology sides, the THEW received contributions from private companies such as AMPS, Cardiacore, Global Instrumentations and iCardiac Technologies. Their contributions include help for data deidentification, and ECG file conversion tools enabling a seamless integration of electrocardiograms into the THEW, while other companies helped us develop tools to distribute this information to the THEW members.

To conclude, the THEW team wishes you a successful and happy New Year 2009.

Jean-Philippe Couderc, PhD
Director of the Telemetric and Holter ECG Warehouse Initiative

In-depth...

23-Dec-2008

Pfizer Contributes Critical Data to the THEW Initiative

Pfizer has agreed to provide the University of Rochester Medical Center (URMC) with a unique set of electrocardiographic data that will help researchers develop new methods to ensure the safety of experimental drugs. This is the first time a major pharmaceutical company has agreed to publicly share

anonymous data from one of its drug safety trials **including data from the drug that was being evaluated**. Pfizer Global Research and Development's Sandwich Laboratory in the United Kingdom released a large set of continuous electrocardiographic (ECG) recordings to the THEW from which more than 1.5 million individual ECGs can be extracted. This data will be extremely valuable because it enables scientists to evaluate the electrical activity in the heart before and after study participants took the drug. The study subjects received a placebo, a control drug known to prolong the repolarization process (moxifloxacin) and a drug that did not reach the market because of its QT prolonging effect. The THEW data sharing agreement requires compliancy with ethics and patient privacy laws; all data in the warehouse have been de-identified and the system is fully compliant with federal privacy (HIPPA) regulations. The Pfizer data has been fully anonymized, or stripped of any information that would enable individual patients to be identified. The THEW team is glad and thankful that Pfizer has chosen the THEW platform for sharing their data with the international scientific community.

More information and press release available at: <http://www.thew-project.org/Alliances.html>

09-Dec-2008**THEW, Roche and Cardiocore Collaboration Enables Key Cardiac Safety Research Milestone**

Roche has agreed to share data from a recently completed Thorough QT study (TQT), with Cardiocore becoming the first core lab to help de-identifying the Holter ECG data for upload to the THEW repository. "We are delighted to contribute these data to the THEW program," said Ignacio Rodriguez, MD, head of Roche's ECG Working Group.... "We hope that this data will help advance the science of cardiac safety monitoring. In striving for innovation, we are fortunate to work with like-minded and supportive partners at the THEW and Cardiocore."

In this thorough QT study, 300 recordings of 24-hour Holter data that were acquired from 76 subjects in a crossover design. High-fidelity continuous electrocardiographic recordings at 1,000 samples per second are provided enabling true one-millisecond resolution. Fully de-identified data from the placebo and positive control periods were shared. The successful submission of both clinical and ECG information to our warehouse solidifies the THEW legal framework for data sharing. More importantly, this data will enable unique research projects for validating and improving precision of current and future ECG technologies. THEW partners will be able to access the Holter ECGs from which more than 2 million standard 12-lead ECG tracings can be extracted.

More information and press release available at: <http://www.thew-project.org/Alliances.html>

03-Dec-2008**Global Instrumentations joins the URMCFDA initiative to enable secured WEB environment technologies for sharing health information from the THEW.**

Global Instrumentation has signed an agreement with the University of Rochester supporting the activities of the THEW. Global Instrumentations has provided supporting technologies to develop the THEW software and to enable worldwide access to clinical and electrocardiographic information using advanced security and encryption algorithms. The THEW software includes plug-in application programming interface (API) for the design and validation of analytic methods independently. The agreement with Global Instrumentations is helping the THEW to distribute worldwide the information contained in its large databases of ECGs and clinical information. We definitely welcome Global Instrumentations as a member and contributor to the THEW initiative.

More information and press release available at: <http://www.thew-project.org/Alliances.html>

16-Dec-2008**AMPS Contributes Key Software Tools to the THEW**

AMPS and the THEW announce an agreement around the sharing of a number of key software programs needed to convert the data uploaded to the THEW repository into a common standard format.

"We are delighted to contribute with our technology to the THEW program," said Fabio Badilini PhD, Chief Scientist at AMPS. He continued, "AMPS in particular provided, among other tools, a powerful

software tool dedicated to the Holter environment, capable to intelligently extract strips from most commercial Holter recordings and produce standard output formats.” AMPS LLC is a member and a contributor to the THEW initiative. The conversion of the data shared by pharmaceutical companies has been greatly facilitated with the AMPS tools. In a couple of months we have loaded more than 800 Holters into the Warehouse which is equivalent in size to 7 million 12-lead standard ECGs.

More information and press release available at: <http://www.thew-project.org/Alliances.html>